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Children's Health Center

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July 3, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Docket Number: 02N-0152

Dear Sir or Madam:

As a pediatrician who cares for infants and children every day, I welcome the opportunity to comment on the relationship between the 1998 Pediatric Rule and the Best Pharmaceuticals for Children Act (P.L. 107-109). As a member of the American Academy of Pediatrics (AAP), I know that the AAP has advocated for appropriately tested and labeled medications for infants, children and adolescents for over 40 years. Securing safe and appropriate drugs for use by children has had a long and laborious history. Significant progress toward pediatric drug studies and labeling has been made over the last five years.

In March 2002 the FDA proposed to suspend the Pediatric Rule. The Pediatric Rule ensures that children are no longer a therapeutic afterthought by the pharmaceutical industry. It is an essential and successful tool in ensuring that children have the quality and quantity of drugs they need. These are the critical issues relevant to children's health:

- **The Pediatric Rule captures drugs and age populations that the Best Pharmaceuticals for Children Act cannot.** The BPCA incentive of additional market exclusivity can only be applied once during the life cycle of a drug. When FDA requests pediatric studies under BPCA, all potential pediatric uses must be anticipated in the request. This request cannot be expanded later if additional studies are needed in very young children or newborns or if a new use is discovered for a drug. Once studies have been completed and the incentive has been granted, there is no obligation on the part of participating companies to generate additional pediatric data. The Pediatric Rule may be invoked in instances where pediatric information is

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essential but the BPCA is no longer available.

- **The Pediatric Rule is ongoing - the Best Pharmaceuticals for Children Act is time-limited.** The BPCA sunsets in 2007. If it is not renewed, history suggests that the industry may not see it within their scope or financial best interest to continue to do pediatric drug studies. The Pediatric Rule will allow pediatric studies to continue.
- **The Pediatric Rule is mandatory - the Best Pharmaceuticals for Children Act is voluntary.** Because BPCA is voluntary, not all sponsors are interested in complying with the terms. The Pediatric Rule applies to all drugs and biologicals whose intended use in pediatrics is the same as adults, thus ensuring appropriate pediatric information.

Thank you for consideration of these comments.

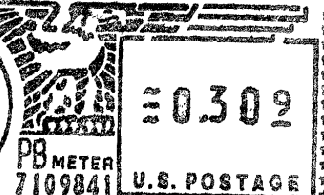
Sincerely,

A handwritten signature in black ink, appearing to read 'Adrian Sandler', with a stylized, flowing script.

Adrian D. Sandler MD
Developmental-Behavioral Pediatrician, Asheville NC
Chair, AAP Committee on Children With Disabilities



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